

IN THE CLAIMS

1. (currently amended) An oral sustained release pharmaceutical comprising:

a plurality of granules having diameters of not more than 1000 μm ,

wherein said granules comprise:

a nucleus granule comprised of beraprost sodium, and

a coating agent coating said nucleus granule, and

wherein said coating agent is comprised of:

a first skin layer containing one or more relatively water-insoluble macromolecular substances selected from the group consisting of ~~water-insoluble alkyl cellulose ether derivatives, water insoluble acrylic polymer derivatives and water-insoluble vinyl derivatives~~ ethyl celluloses, butyl celluloses, polyvinyl acetates, polyvinyl butyrates, and acrylic acid-methacrylic acid copolymers, and

a second skin layer containing one or more hot-melt low-melting substances, said hot-melt low-melting substances having a softening point of not higher than 70°C.

2. (cancelled)

3. (cancelled)

4. (previously presented) The oral sustained release pharmaceutical composition of claim 1, wherein said one or more hot-melt low-melting substances are selected from the group consisting of higher alcohols, higher fatty acids, higher fatty acid glycerin esters, waxes and saturated hydrocarbons.

5. (previously presented) The oral sustained release pharmaceutical composition of claim 1, wherein a weight ratio of said first skin layer to said second skin layer ranges from about 1:9 to about 9:1.

6. (currently amended) A process for producing an oral sustained release pharmaceutical composition comprising:

a) applying a coating comprised of beraprost sodium to a granule,

b) applying a coating comprised of one of a hot-melt low melting substance or of a relatively water-insoluble macromolecular substance to said beraprost sodium coated granule, thereby providing a first skin layer,

c) applying the other of said hot-melt low-melting substance or said relatively water-insoluble macromolecular substance to said first skin layer, thereby providing a second skin layer,

d) curing said first and second skin layers to form films, and

e) encapsulating a plurality of said coated granules in a capsule

wherein said hot-melt low-melting substance has a softening point of not higher than 70°C and wherein said water-insoluble macromolecular substance is selected from the group consisting of ethyl celluloses, butyl celluloses, polyvinyl acetates, polyvinyl butyrates, and acrylic acid-methacrylic acid copolymers ~~water insoluble alkyl cellulose ether derivatives, water insoluble acrylic polymer derivatives and water insoluble vinyl derivatives.~~

7. (previously presented) The oral sustained release pharmaceutical composition of claim 5, wherein said weight ratio ranges from about 3:7 to about 7:3.

8. (new) An oral sustained release pharmaceutical beraprost sodium composition with high bioavailability and pH sensitivity comprising:

a plurality of granules having diameters of not more than 1000 μm ,

wherein said granules comprise:

a nucleus granule comprised of beraprost sodium, and

a coating agent coating said nucleus granule, and

wherein said coating agent is comprised of:

a first skin layer containing one or more relatively water-insoluble macromolecular substances selected from the group consisting of ethyl celluloses, butyl celluloses, polyvinyl acetates, polyvinyl butyrates, and acrylic acid-methacrylic acid copolymers, and

a second skin layer containing one or more hot-melt low-melting substances, said hot-melt low-melting substances having a softening point of not higher than 70°C, wherein said first and second skin layers are selected to provide a pH-independent release of said beraprost sodium.